

**§ 558.618 Tilmicosin.**

(a) *Approvals.* Type A medicated articles: 90.7 grams of tilmicosin (as tilmicosin phosphate) per pound (200 grams per kilogram) to 000986 in § 510.600(c) of this chapter.

(b) *Special considerations.* Do not use in any feed containing bentonite.

(c) *Related tolerances.* See § 556.735 of this chapter.

(d) *Conditions of use.* It is used in swine feed as follows:

(1) *Amount per ton.* 181 grams to 363 grams tilmicosin.

(2) *Indications for use.* For the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

(3) *Limitations.* For use in swine feed only. The safety of tilmicosin has not been established in pregnant swine or swine intended for breeding purposes. Feed continuously as the sole ration for 21-day period, beginning approximately 7 days before an expected disease outbreak. Withdraw 7 days before slaughter. Federal law restricts this drug to use under the professional supervision of a licensed veterinarian. Any animal feed bearing or containing this drug shall be fed to animals only by or upon a lawful veterinary feed directive (VFD) issued by a licensed veterinarian in the course of the veterinarian's professional practice. VFD's for tilmicosin phosphate shall not be refilled.

(4) *VFD Requirements.* This drug and any article or feed manufactured from it shall bear the following cautionary statements: "Caution: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice." A VFD shall contain the following information: The name, address, and phone number of the veterinarian and the client; identification of the animals to be treated, including, identification of the species, number of animals, and the location of the animals; date of treatment and, if different, date of prescribing the VFD drug; the condition or disease being di-

agnosed or treated; name of the animal drug; level of animal drug in feed and amount of feed; feeding instructions with withdrawal time; any special instructions and cautionary statements necessary for use of the drug in conformance with the approval; expiration date of VFD; number of refills, if permitted by approval; signature of the veterinarian; veterinarian's license number and name of the State issuing the license.

[61 FR 68148, Dec. 27, 1996; 62 FR 15391, Apr. 1, 1997]

**§ 558.625 Tylosin.**

(a) *Specifications.* Tylosin is the antibiotic substance produced by growth of *Streptomyces fradiae* or the same antibiotic substance produced by any other means. Tylosin, present as the phosphate salt, conforms to the appropriate antibiotic standard. Tylosin contains at least 95 percent tylosin as a combination of tylosin A, tylosin B, tylosin C, and tylosin D of which at least 80 percent is tylosin A as determined by a method entitled "Determination of Factor Content in Tylosin by High Performance Liquid Chromatography," which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20001.

(b) *Approvals.* Type A medicated article levels of tylosin granted to firms as sponsor(s) and identified by drug listing numbers in § 510.600(c) of this chapter for the specific usage indicated in paragraph (f) of this section.

(1) To 000986: 10, 40, 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(2) To 051359: 1, 2, 4, 5, 8, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(3) To 043733: 20 and 40 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(4) [Reserved]

(5) To 017800: 0.4, 0.8, 1, and 8 grams per pound, paragraph (f)(1)(vi)(a) of this section; 10 and 40 grams per pound,

paragraphs (f)(1) (i) through (vi) of this section.

(6)–(7) [Reserved]

(8) To 035369: 4 and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section; 10 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(9) To 043727: 4 grams per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(10) To 017519: 0.4, 0.8, and 1.6 grams per pound, paragraph (f)(1)(vi)(a) of this section; 20, 40, and 100 grams per pound, paragraphs (f)(1)(i) through (f)(1)(vi) of this section.

(11) [Reserved]

(12) To 021930: 2 grams per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(13) To 035393: 0.4 and 2 grams per pound; paragraph (f)(1)(vi)(a) of this section.

(14) To 016968: 1, 2, 4, 8, and 10 grams per pound, paragraphs (f)(1) (i), (iii), (iv), and (vi) of this section; 20, 25, 40, and 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(15) [Reserved]

(16) To 049768: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(17) To 021780: 0.8 gram per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(18) [Reserved]

(19) To 033999: 10 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(20)–(21) [Reserved]

(22) To 026282: 10 grams per pound; paragraph (f)(1)(vi)(a) of this section.

(23)–(24) [Reserved]

(25) To 000069: 4, 8, and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section; 20 and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(26)–(30) [Reserved]

(31) To 029341: 5 grams per pound; paragraph (f)(1)(vi)(a) of this section.

(32) [Reserved]

(33) To 034936: 0.8 and 2 grams per pound, paragraph (f)(1)(vi)(a) of this

section; 4, 8, and 10 grams per pound, paragraphs (f)(1)(i), (iii), (iv), and (vi) of this section; 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section; 100 grams per pound, paragraphs (f)(1) (i), (ii), (iii), (iv), and (vi) of this section.

(34) To 028260: 0.8 gram per pound, paragraph (f)(1)(vi)(a) of this section.

(35) To 039741: 2 and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(36)–(37) [Reserved]

(38) To 053740: 1 gram per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(39) To 050604: 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(40) To 035955: 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(41) [Reserved]

(42) To 010439: 0.4, 0.5, and 2 grams per pound, paragraph (f)(1)(vi) (a) of this section; 5, 10, 20, and 40 grams per pound, paragraph (f)(1)(i) through (vi) of this section.

(43)–(44) [Reserved]

(45) To 017139: 4 and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(46)–(47) [Reserved]

(48) To 017790: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(49)–(51) [Reserved]

(52) To 017519: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(53) [Reserved]

(54) To 046573: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(55)–(56) [Reserved]

(57) To 028459: 0.4 and 10 grams per pound; paragraph (f)(1)(vi)(a) of this section.

(58)–(62) [Reserved]

(63) To 046987: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(64)–(65) [Reserved]

(66) To 024174: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(67) To 027190: 2 grams per pound; paragraph (f)(1)(vi)(a) of this section.

(68) To 017473: 10 and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(69)–(72) [Reserved]

(73) To 035098: 0.33 and 0.67 gram per pound, paragraph (f)(1)(vi)(a) of this section; 0.8, 1, 2, and 10 grams per pound, paragraphs (f)(1) (i) and (vi) (a), (b) and (d) of this section; 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(74)–(76) [Reserved]

(77) To 050639: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(78) To 050972: 0.36, 0.4, 0.72, and 0.8 gram per pound, paragraph (f)(1)(vi)(a) of this section; 1 gram per pound, paragraphs (f)(1)(vi) (a), (b), and (d) of this section.

(79) To 012286: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(80) To 049685: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(81)–(82) [Reserved]

(83) To 046573: 5-, 10-, 20-, and 40-grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(84) [Reserved]

(85) To 047126: 10, 40, and 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(86)–(88) [Reserved]

(89) To 053389: 5, 10, 20, and 40 grams per pound, paragraph (f)(1) (i) through (vi) of this section.

(c)–(d) [Reserved]

(e) *Related tolerances.* See § 556.740 of this chapter.

(f) *Conditions of use.* (1) It is used in animal feeds as follows:

(i) *For beef cattle—(a) Amount per ton.* 8–10 grams.

(b) *Indications for use.* For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*.

(c) *Limitations.* As tylosin phosphate; each animal must receive not more than 90 milligrams per day and not less than 60 milligrams per day; feed continuously as sole ration.

(ii) *Broiler chickens—(a) Amount per ton.* Tylosin, 800–1000 grams.

(b) *Indications for use.* To aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum*.

(c) *Limitations.* As tylosin phosphate; withdraw 5 days before slaughter; administer in feed to chickens 0 to 5 days of age, follow with second administration in feed for 24–48 hours at 3 to 5 weeks of age.

(iii) *Chickens—(a) Amount per ton.* Tylosin, 4–50 grams.

(1) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(2) *Limitations.* As tylosin phosphate.

(iv) *Laying chickens—(a) Amount per ton.* Tylosin, 20–50 grams.

(b) *Indications for use.* For improved feed efficiency.

(c) *Limitations.* As tylosin phosphate.

(v) *Replacement chickens—(a) Amount per ton.* Tylosin, 1,000 grams.

(b) *Indications for use.* To aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum*.

(c) *Limitations.* As tylosin phosphate; withdraw 5 days before slaughter; administer in feed to chickens 0 to 5 days of age, follow with second administration in feed for 24 to 48 hours at 3 to 5 weeks of age.

(vi) *Swine—(a) Amount per ton.* Tylosin, 10–100 grams.

(1) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(2) *Limitations.* As tylosin phosphate; continuous use as follows: *Grams per ton:* 20–100, prestarter or starter; 20–40, grower; 10–20, finisher.

(b) *Amount per ton.* Tylosin, 40–100 grams.

(1) *Indications for use.* Prevention of swine dysentery (vibronic).

(2) *Limitations.* Use 100 grams per ton for at least 3 weeks followed by 40 grams per ton until market weight; as tylosin phosphate.

(c) *Amount per ton.* Tylosin, 40–100 grams.

(1) *Indications for use.* Treatment and control of swine dysentery (vibronic).

(2) *Limitations.* Administer in feed as tylosin phosphate after treatment with tylosin in drinking water as tylosin base; 0.25 gram per gallon in drinking water for 3–10 days, 40–100 grams per ton in feed for 2–6 weeks.

(d) *Amount per ton.* Tylosin, 100 grams.

(1) *Indications for use.* Maintaining weight gains and feed efficiency in presence of atrophic rhinitis.

(2) *Limitations.* As tylosin phosphate.

(2) Tylosin may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Hygromycin B as in § 558.274.

(ii) Melengestrol acetate alone or in combination with certain ionophores in accordance with § 558.342.

(iii) [Reserved]

(iv) Monensin in accordance with § 558.355.

(v) Pyrantel tartrate in accordance with § 558.485.

(e) *Amount per ton.* Tylosin 100 grams. (1) *Indications for use.* Prevention and/or control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*.

(2) *Limitations.* As tylosin phosphate, administer for 21 days.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.625, see the List of CFR Sections Affected in the Finding Aids section of this volume.

#### § 558.630 Tylosin and sulfamethazine.

(a) [Reserved]

(b) *Approvals.* Type A medicated article levels, a combination of equal amounts of tylosin and sulfamethazine, granted to firms as sponsor(s) and identified by drug listing numbers in § 510.600(c) of this chapter for the conditions of use indicated in paragraph (f) of this section.

(1) To 000986: 40 grams per pound each, paragraph (f)(2)(i).

(2) To 000986: 10 grams per pound each, paragraph (f)(2)(i).

(3) To 017519: 10 grams per pound each, paragraph (f)(2)(ii) of this section.

(4) To 021780: 2 grams per pound each, paragraph (f)(2)(ii) of this section.

(5) To 017800: 40 grams per pound each, paragraph (f)(2)(ii) of this section.

(6) To 017139: 4, 10, or 20 grams per pound each, paragraph (f)(2)(ii) of this section.

(7) To 021930: 2 grams per pound each, paragraph (f)(2)(i) of this section; 5, 10, 20, or 40 grams per pound each, paragraph (f)(2)(ii) of this section.

(8) To 017519, 026186: 5 or 10 grams per pound each, paragraph (f)(2)(ii) of this section.

(9) [Reserved]

(10) To 010439, 011749, 016968, 017473, 017519, 017790, 021780, 024174, 030841, 034936, 035098, 043727, 043733, 046573, 046987, 050568, 050639, and 051359, 053389: 5, 10, 20, or 40 grams per pound each, paragraph (f)(2)(ii) of this section.

(c)–(d) [Reserved]

(e) *Related tolerances.* See §§ 556.670 and 556.740 of this chapter.

(f) *Conditions of use.* It is used in feed for swine as follows:

(1) *Amount per ton.* Tylosin, 100 grams plus sulfamethazine, 100 grams.

(2) *Indications for use.* (i) Maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis; prevention of swine dysentery (vibriotic); control of swine pneumonias caused by bacterial pathogens (*P. multocida* and/or *C. pyogenes*); for reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E Streptococci. Only the sulfamethazine portion of this combination is active in controlling jowl abscesses.

(ii) Maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis; prevention of swine dysentery (vibriotic); control of swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Corynebacterium pyogenes*).

(3) *Limitations.* As tylosin phosphate; withdraw 15 days before slaughter.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.630, see the List of CFR Sections Affected in the Finding Aids section of this volume.

#### § 558.635 Virginiamycin.

(a) [Reserved]

(b) *Approvals.* Type A medicated articles. (1) 1.1 percent activity (5 grams per pound), 2.2 percent activity (10 grams per pound), 4.4 percent activity (20 grams per pound), 11 percent activity (50 grams per pound), and 50 percent activity (227 grams per pound) used as in paragraph (f) of this section; and 30 percent activity (136.2 grams per